
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 13, 2022

EYENOVIA, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38365
(Commission
File Number)

47-1178401
(IRS Employer
Identification No.)

295 Madison Avenue, Suite 2400, New York, NY 10017
(Address of Principal Executive Offices, and Zip Code)

(917) 289-1117
Registrant's Telephone Number, Including Area Code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	(Trading Symbol)	(Name of each exchange on which registered)
Common stock, \$0.0001 par value	EYEN	The Nasdaq Stock Market (Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒ x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On December 13, 2022, Eyenovia, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration has accepted for review the Company’s New Drug Application for MydCombi, the Company’s proprietary, first-in-class combination of tropicamide and phenylephrine for in-office-pupil dilation.

A copy of the press release is filed hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Eyenovia, Inc. Press Release dated December 13, 2022.</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 13, 2022

EYENOVIA, INC.

/s/ John Gandolfo

John Gandolfo

Chief Financial Officer



Eyenovia Announces FDA Acceptance of New Drug Application for MydCombi™ for In-Office Pupil Dilation

Agency assigns PDUFA action date of May 8, 2023

MydCombi™, if approved, would be the first product incorporating Eyenovia's novel Optejet® drug delivery technology

Company also announced receipt of California Medical Device Manufacturing license

NEW YORK—December 13, 2022—Eyenovia, Inc. (NASDAQ: EYEN), a pre-commercial ophthalmic technology company developing the Optejet® delivery system for use both in connection with its own drug-device therapeutic programs for mydriasis, presbyopia and pediatric progressive myopia as well as out-licensing for additional indications, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for MydCombi™ ophthalmic spray. MydCombi™ is a drug-device combination product that comprises the company's proprietary, first-in-class combination of tropicamide and phenylephrine for in-office pupil dilation (mydriasis), administered via the investigational Optejet® drug delivery technology.

The agency has assigned the resubmitted NDA a standard review with a Prescription Drug User Fee Act (PDUFA) target action date of May 8, 2023. The FDA also indicated that it is currently not planning to hold an advisory committee meeting to discuss the application.

"Acknowledgement of our MydCombi NDA is a significant step forward in our quest to bring a paradigm change in the way that topical eye drugs are developed and delivered, and we look forward to working with FDA during its review," stated Michael Rowe, Chief Executive Officer of Eyenovia. "If approved, MydCombi would be the first commercial product to leverage our proprietary Optejet drug delivery device, which we believe could bode well not only for our other internal development programs for presbyopia and progressive myopia but our ongoing partnering discussions as well."

The MydCombi NDA is supported by two completed Phase 3 clinical trials, MIST-1 and MIST-2. The MIST-1 trial (NCT03751631) compared MydCombi to phenylephrine (PE) alone and tropicamide (TR) alone, while MIST-2 (NCT03751098) compared MydCombi to placebo. All treatments were administered using Eyenovia's Optejet technology.

Eyenovia Announces Receipt of California Medical Device Manufacturing License

Eyenovia also announced today that on November 30th, the company was awarded its California Medical Device Manufacturing license, allowing manufacturing operations to formally commence at its new state-of-the-art facility in Redwood City, CA.

About Mydcombi™ for Mydriasis

Mydcombi is Eyenovia's investigational, first-in-class fixed-dose-combination product (tropicamide 1% and phenylephrine 2.5% ophthalmic spray) for pharmacologic mydriasis (eye dilation), which is targeted to improve the efficiency of the estimated 100 million office-based comprehensive eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. Developed as a micro-formulation for use without anesthetic, Eyenovia believes Mydcombi will help improve the efficacy, tolerability, and efficiency of pharmacologic mydriasis. Mydcombi has been licensed to Arctic Vision (Hong Kong) Limited in Greater China and South Korea.



About Optejet® and Microdose Array Print (MAP™) Therapeutics

Eyenovia's Optejet microdose formulation and delivery platform for ocular therapeutics uses high-precision piezo-print technology to deliver 6-8 µL of drug, consistent with the capacity of the tear film of the eye. We estimate the volume of ophthalmic solution administered with the Optejet is less than 20% of that delivered using conventional eyedroppers, thus reducing overdosing and exposure to drug and preservatives. Eyenovia's patented microfluidic ejection technology is designed for fast and gentle ocular surface delivery, where solution is dispensed to the ocular surface in approximately 80 milliseconds, beating the ocular blink reflex. Successful use of the Optejet has been demonstrated more than 85% of the time after basic training in a variety of clinical settings compared to 40 – 50% historically seen with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print (MAP™) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for mydriasis, presbyopia and myopia progression. For more information, visit Eyenovia.com.

The Eyenovia Corporate Information slide deck may be found at ir.eyenovia.com/events-and-presentations.

Forward-Looking Statements

Except for historical information, all of the statements, expectations and assumptions contained in this press release are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions, including estimated market opportunities for our product candidates and platform technology. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and in some cases are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in documents which we file with the U.S. Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to, among other things: risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could still be adversely impacted by COVID-19 and resulting social distancing), timing, progress and results of such trials; the timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our product candidates; the potential impacts of COVID-19 on our supply chain; the potential advantages of our product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; intellectual property risks; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; and our competitive position. Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.



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